

**DEPARTMENT OF HEALTH SERVICES
BUREAU OF EMERGENCY MEDICAL SERVICES**

**SUBSTANTIVE POLICY STATEMENT
#SP-073-PHS-EMS**

Approval of Medical Devices

This substantive policy statement is advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona Administrative Procedure Act. If you believe that this substantive policy statement does impose additional requirements or penalties on regulated parties, you may petition the agency under Arizona Revised Statutes § 41-1033 for a review of the statement.

The purpose of this substantive policy statement is to notify the public of the Arizona Department of Health Services' (ADHS's) position on the necessity of ADHS's approving medical devices for use by emergency medical technicians (EMTs) in the prehospital emergency medical services (EMS) environment.

A.R.S. § 36-2205(A) requires ADHS, in consultation with the EMS Medical Director, EMS Council, and the Medical Direction Commission, to establish "protocols, which may include training criteria, governing the medical treatments, procedures, medications and techniques which may be administered or performed by each class of emergency medical technician."

The statute does not require ADHS to establish protocols governing the medical devices that may be used by EMTs in the prehospital EMS setting. Therefore, ADHS believes that it is unnecessary for ADHS to approve a specific medical device for use by EMTs in the prehospital EMS environment if the device has FDA approval and is used to accomplish or facilitate a treatment, procedure, or technique that is already within the scope of practice of the class of EMTs that will be using the device.

***Effective January 1, 2006
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